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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,690	03/10/2004	Madhwa H.G. Raj	Raj 02M27.1	7199

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PATENT DEPARTMENT
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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,690	RAJ ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed October 9, 2006, is acknowledged and has been entered.

2. Upon further consideration, the restriction requirement mailed July 11, 2006 has been VACATED and a new restriction requirement follows.

3. Claims 1-23 are pending in the application and are currently subject to restriction.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 2, drawn to a method for inhibiting prostate cancer, said method comprising administering to a mammal one or more antibodies that bind compounds selected from riboflavin carrier protein, folic acid binding protein, and retinol binding protein, classified, for example, in class 424, subclass 130.1.

II. Claims 3-4, drawn to a method for inhibiting prostate cancer, said method comprising administering to a mammal one or more antisense oligonucleotides that inhibit the translation of compounds selected from riboflavin carrier protein, folic acid binding protein, and retinol binding protein, classified, for example, in class 514, subclass 44.

III. Claim 5, drawn to a method for inhibiting prostate cancer, said method comprising administering to a mammal one or more double-stranded RNA olignucleotides that inhibit the translation of compounds selected from riboflavin carrier protein, folic acid binding protein, and retinol binding protein, classified, for example, in class 514, subclass 44.

IV. Claim 10, drawn to a method for inhibiting prostate cancer in a mammal afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous riboflavin carrier protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

V. Claim 11, drawn to a method for inhibiting prostate cancer in a mammal afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous folic acid binding protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

VI. Claim 12, drawn to a method for inhibiting prostate cancer in a mammal afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous retinol binding protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

VII. Claims 14, drawn to a method for preventing prostate cancer in a mammal that is not known to be afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous riboflavin carrier protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

VIII. Claim 15, drawn to a method for preventing prostate cancer in a mammal that is not known to be afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous folic acid binding protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

IX. Claim 16, drawn to a method for preventing prostate cancer in a mammal that is not known to be afflicted with prostate cancer, said method comprising immunizing the mammal against heterologous retinol binding protein or peptide subunits thereof, classified, for example, in class 424, subclass 184.1.

X. Claim 18, drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-immunogen conjugate, wherein the vitamin is riboflavin, classified, for example, in class 514, subclass 79.

XI. Claim 19, drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-immunogen conjugate, wherein the vitamin is folate, classified, for example, in class 514, subclass 85.

XII. Claim 20, drawn to a method for inhibiting prostate cancer comprising targeting prostate cancer cells with a vitamin-immunogen conjugate, wherein the vitamin is retinol, classified, for example, in class 514, subclass 11.

5. Claims 1, 6-9, 13, 17 and 21-23 are linking claims. Claims 1 and 6-8 link Groups I-III. Claims 9 and 22 link the inventions of Groups IV-VI. Claims 13 and 23 link the inventions of Groups VII-IX. Claims 17 and 21 link the inventions of groups X-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The inventions are distinct, each from the other because of the following reasons:

Each of the the inventions of Groups I-XII are materially different processes, comprise different process steps, involve the measurement of different endpoints, and/or have different objectives; and for these reasons, each is patentably distinct from the others. For example, the invention of Group IV is a method for inhibiting prostate cancer in a mammal afflicted with prostate cancer comprising immunization against heterologous riboflavin carrier protein or peptide subunits thereof, whereas the invention of Group VII is a method for inhibiting prostate cancer in a mammal that is not known to be afflicted with prostate cancer comprising immunization against heterologous riboflavin carrier protein or peptide subunits thereof. As such, different patient populations are treated, with differing objectives to either inhibit prostate cancer in a mammal with the disease or prevent prostate cancer in a mammal without the disease. As another example, although the inventions of Groups I-IV are each processes for inhibiting prostate cancer, each is a materially different process because each comprises administering to a mammal a different antagonist; and each of these different antagonists (e.g., antibodies, antisense oligonucleotides) is materially and structurally different from the others and has or causes a different effect, so as to have a mode of operation differing from the others. As such, the practice of each of the inventions of Groups I-IV to achieve the claimed objective has different criteria for success; and for similar reasons, the remaining inventions are also expected to have markedly different criteria for success.

Because the inventions of Groups I-XII have different objectives, and/or are materially different processes, and/or comprise different process steps, including the measurement of different endpoints or the establishment of different correlations, each different method has achieved a different status in the art, as evidenced in some instances by their different classifications and/or, in other instances, by their art-recognized divergences. Consequently, the search required to consider any one of the inventions of Groups I-XII is not the same,

nor is it coextensive with the search necessary to consider any of the others. As such, consideration of claims directed to any one of the different inventions would require a search that differs from the search needed to consider claims directed to any other invention; and any need to perform more than one search would constitute a serious burden.

Since the inventions of Groups I-XII have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

7. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to a patentably distinct species of the inventions of Groups I, II, or III, wherein said compounds are selected from the group consisting of riboflavin carrier protein, folic acid binding protein, and retinol binding protein.

Each of these compounds has a different structure and function; and furthermore, each is expected to have a different association with the etiology and/or pathology of prostate cancer. In addition, it is expected that administering antagonists of one or any combination of these compounds will achieve therapeutic effects that differ from those achieved by administering antagonists to any other one or combination of compounds. For these reasons, each of the different species of invention are patentably distinct.

Because each species of invention is patentably distinct from the others for these reasons, different searches would be required to determine the patentability of each, as the search required to consider claims directed to any one species is not the same, nor is it coextensive with the search necessary to consider claims directed to any other species; and performing more than one search would be unduly burdensome.

If applicant elects any of Groups I-III, applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of invention for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consistent with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or invention.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

STEPHEN L. RAWLINGS, PH.D.
PRIMARY EXAMINER